

(19)



Europäisches Patentamt
European Patent Office
Office européen des brevets



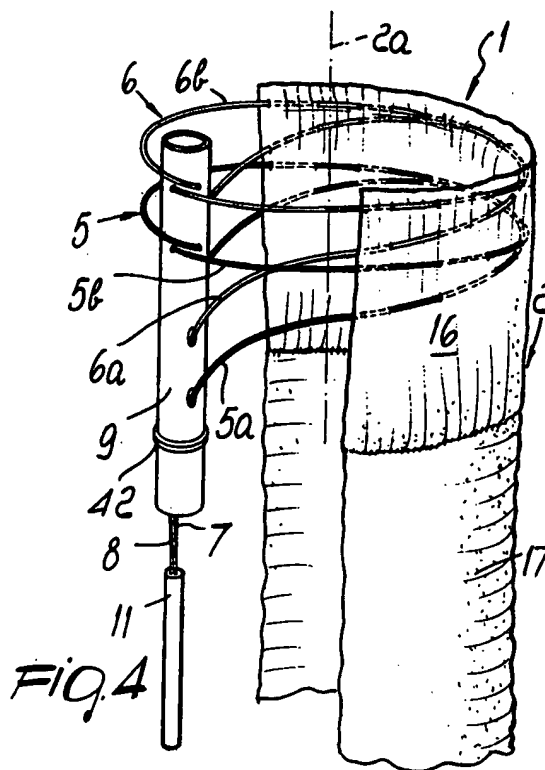
(11) Publication number:

0 664 107 A1

(12)

EUROPEAN PATENT APPLICATION(21) Application number: **95100498.5**(51) Int. Cl.⁸: **A61F 2/06**(22) Date of filing: **16.01.95**(30) Priority: **19.01.94 IT MI940066**(43) Date of publication of application:
26.07.95 Bulletin 95/30(84) Designated Contracting States:
DE FR GB(71) Applicant: **NAZARI, Stefano**
Via Bignanico, 12/C
I-22100 Como (IT)(72) Inventor: **NAZARI, Stefano**
Via Bignanico, 12/C
I-22100 Como (IT)(74) Representative: **Modlano, Guido, Dr.-Ing. et al**
Modlano & Associati S.r.l.
Via Meravigli, 16
I-20123 Milano (IT)(54) **Vascular prosthesis and device for its application.**

(57) Vascular prosthesis (1) for the substitution or internal lining of blood vessels of medium and large diameter and to a device for its application which includes a tubular body (2) of biocompatible material that is associated with, at least at one longitudinal end, at least one body at annular development (3), that is disposed substantially coaxial to the tubular body (2) and that is radially expandible for the engagement of the tract of the tubular body (2), which contains the body at annular development (3), against the inner walls of a blood vessel (4) proximal to the segment of the vessel to be substituted, or internally lined, with the prosthesis (1). The body at annular development includes at least one loop (5,6) of at least one wire (7,8) elastically flexible, which is slideably mounted on a support (9) associated to a lateral portion of the tubular body (2). This wire (7,8) is slideable with respect to the support (2) mentioned before to vary the amplitude of the loop (5,6) and tools are predisposed to contrast the wire (7,8) sliding in respect to the support (2) in order to maintain the expansion or contraction, given to the loop (5,6) by means of the controlled sliding of the wire (7,8) relatively to the support (2), at ceasing of the force generating the sliding.



BEST AVAILABLE COPY

EP 0 664 107 A1

The present invention consists of a vascular prosthesis for the substitution or internal lining of blood vessels of medium and large diameter and of a device for its application.

Aneurisms of various origin and traumatic lesions are the most frequent conditions requiring thoracic and abdominal aortic prosthetic substitution. Current technique includes the surgical exposure of the aortic segment to be replaced; both ends of the aneurysm are isolated and clamped to stop the blood flow; the vessel is opened and a tubular conduit of biocompatible material is interposed and manually sutured at both ends.

Most complications of descending thoracic aorta prosthetic substitution (paraplegia, liver and renal injury) are due to ischemic lesions of distal organs (spinal cord, liver and kidney) during the blood flow interruption phase and the incidence is proportional to its duration. Other complications are related to the manoeuvres taken to compensate the haemodynamic modifications induced by clamping (extracorporeal circulation, heparinization, etc.).

A further source of complications is the suture line which can bleed at the operative table or cause pseudoaneurism in the late postoperative period; these problems are enhanced by the alterations of the aortic wall due to the primary disease.

The main aim of this invention is to solve these problems using a vascular prosthesis that can be applied very quickly greatly reducing the duration of the interruption of the blood flow in the segment to be substituted.

Within the above aim, an object of the invention is that of realizing a prosthesis that can be applied also without blood flow interruption.

Another aim of the invention is that of realizing a prosthesis that can be applied without requiring necessarily the surgical exposition of the blood vessel.

Another aim of the invention is to realize a prosthesis that can be applied to the vessel without surgical suture.

A further aim is that of realizing a device that would allow the positioning and the application of the vascular prosthesis, as invented, without interruption of the blood flow in the substituted vascular segment.

This aim and these and other objects which will become apparent hereinafter are achieved by a vascular prosthesis for the substitution or internal lining of blood vessels of medium and large diameter characterized by the fact of comprising a tubular body of biocompatible material associated, in proximity of at least one of its longitudinal ends, with at least one body at annular development disposed substantially coaxial to said tubular body and radially expandible for the engagement of the tract of said tubular body, containing said body at

annular development, against the internal walls of a blood vessel proximal to the segment to be substituted or internally lined, with the prosthesis, said body at annular development being constituted of at least one loop of at least one wire elastically flexible slidably mounted on a support associated to a lateral portion of said tubular body, said wire being slideable with respect to said support in order to vary the amplitude of said loop, tools for contrast of sliding of said wire relatively to said support being provided in order to maintain the expansion or contraction, given to said loop by the controlled sliding of said wire relatively to said support, at the ceasing of the force generating the sliding.

For the application of the vascular prosthesis according to the invention, when one desires to operate without blood flow interruption, a device is preferably used, characterized by the fact of comprising a flexible tubular support that can be inserted into the lumen of a blood vessel distal to the segment to be substituted or internally lined with said prosthesis, said tubular support being provided, at its distal end, intended to be inserted into the blood vessel, with tools for retaining said support and, at its proximal end, intended to be sited externally to said vessel, with controlling tools which are connected, by connection tools sliding internally to said tubular support, to said at least one wire for its sliding relatively to said support for a variation of the amplitude of said at least one loop for the radial expansion or contraction of said body at annular development, tools for deactivation of said tools for retaining said support being provided and said connecting tools being releasable at command by said at least one wire in order to leave into the vessel the prosthesis after its application.

Further features and advantages of the invention will be apparent from the following description of a preferred, though not exclusive embodiment of the vascular prosthesis according to the invention, as well as of a device for its application, illustrated in the accompanying illustrative, not limitative drawings wherein:

figure 1 illustrates the body at annular development of the prosthesis according to the invention in perspective view in position radially contracted;

figure 2 illustrates the body at annular development of the prosthesis according to the invention in perspective view in position radially expanded;

figure 3 shows a particular enlarged and exploded of figures 1 and 2;

figure 4 illustrates a detail enlarged and partially in section of the prosthesis according to the invention;

figure 5 is a schematic axial section of the device for the application of the prosthesis according to the invention;

figure 6 illustrates a detail enlarged, in perspective and partially sectioned view, of the device for the application of the prosthesis according to the invention;

figure 7 illustrates a detail enlarged, in perspective and partially sectioned view, of the device;

figures between 8 and 11 illustrate the device in proximity to its proximal end in different functioning conditions;

figure 12 schematically illustrates the insertion of the prosthesis according to the invention into a blood vessel;

figure 13 is an enlarged section of figure 12 carried out along the axis XIII-XIII;

figure 14 illustrates the radial expansion phase of the body at annular development of the prosthesis inside the blood vessel;

figure 15 illustrates a detail enlarged of figure 14;

figure 16 illustrates the device and the prosthesis at the end of its application;

figure 17 illustrates, in perspective view partially sectioned, a variant of execution of the prosthesis according to the invention.

With reference to the cited figures, the vascular prosthesis according to the invention, indicated generally by the reference numeral 1, comprises a tubular body 2 realized in synthetic biocompatible material, for example with materials commercially known as dacron or teflon, that is associated, in correspondence of at least one of its longitudinal ends, with at least one body at annular development 3 which is disposed substantially coaxial to the tubular body 2 and which is radially expandible in order to obtain the engagement of the tract of the tubular body 2, which contains the body at annular development 3, against the inner walls of a blood vessel 4 proximal to the tract of the vessel to be substituted or internally lined with the prosthesis.

According to the invention, the body at annular development 3 consists of at least one loop 5, 6 of a wire 7, 8 which is elastically flexible and which is mounted in a sliding way on a support 9 associated to a lateral portion of the tubular body 2 parallel to the axis 2a of tubular body 2. The wire 7, 8 is sliding relatively to the support 9 in order to vary the amplitude of loop 5, 6 or to radially increase or decrease the occupancy of the tract of tubular body 2 that contains the loop 5, 6, and tools are provided to contrast the sliding of wire 7, 8 relatively to the support 9, in such a way that it is maintained the expansion or the contraction, given to the loop 5, 6 by means of the controlled sliding of wire 7, 8 relatively to the support 9, at the

ceasing of the force generating the sliding.

Preferably two wires 7, 8, in harmonic stainless steel are provided, which describe a double loop each, respectively 5 and 6 and each of these double loops presents: a first tract 5a, 6a which comes out from the support 9 along a direction which is inclined in respect to an ideal plane transversal to the axis 2a of the tubular body 2, a second tract 5b, 6b, at annular development, which is bound to the support 9 in a zone that is spaced out of the zone from which comes out the first tract 5a, 6a, and which develops in a plane which is substantially perpendicular to the axis 2a of the tubular body 2, and a third tract 5c, 6c that re-enter into the support 9 in a zone that is proximal to the zone from which comes out the first tract 5a, 6a.

The support 9 is preferably constituted by a body substantially cylindric, preferably hollow, and wires 7, 8 come out laterally from the support 9 to make the double loops 5, 6.

Advantageously, the double loops 5, 6 are spaced between them in a direction which is parallel to the axis 2a of the tubular body 2, or in direction parallel to the axis 9a of the support 9, spacing the holes through whom the tracts of wires 7, 8 come out laterally from the support 9.

It should be noted that the connection of the second tract 5b, 6b of the loops 5, 6 to the support 9 is obtained by means of multiple passages of wire 7, 8 which make the loops 5, 6 through the support 9 in a position which is properly spaced from the position of the holes through whom wires 7, 8 come out from support 9 in such a way that the second tract 5b, 6b of the loops is maintained in a plane which is substantially perpendicular to the axis 2a of the tubular body 2 without significant variation during the use.

The tools for contrast of the sliding of the wires 7, 8 relatively to the support 9, in order to maintain the given radial expansion or contraction of the loops 5, 6, are constituted by the friction resulting from the passage through the support 9 of the wires 7, 8. This friction, which is depending from the dimension and configuration of the holes defined in the support 9 and through whom the wires 7, 8 pass, as well as from the material constituting the support 9 in relation with the material by which are realized the wires 7, 8, can provide in any way a sufficient resistance to undesired accidental contraction or expansion of the loops 5, 6.

Advantageously tools are provided for the positioning of one of the double loops 5 in respect to the other 6. These tools for positioning comprise segments of wire 10, also made of harmonic stainless steel, that connect each other the second tract 5b of the loop 5 with the second tract 6b of the loop 6 in such a way that they contrast efficiently the flexions of the second tract 5b, 6b of the loops

and they maintain them in planes substantially parallel to each other and substantially perpendicular to the axis 2a of the tubular body 2.

The ends of the wires 7 and 8 that constitute the loops 5 and 6 come out from an axial end of the support 9 and are associated, jointly, to a little cylinder block of manoeuvre 11 that is mobile at command relatively to the support 9 in order to cause the sliding of wires 7, 8 to obtain a variation of the amplitude of the loops 5 and 6.

More in detail, the four ends of the wires 7 and 8 are connected to the little cylinder block of manoeuvre 11 by inserting them previously in a sleeve 12, screw-threaded outside, that gives room just sufficient to contain the four ends of the wires 7 and 8, and folding, after having passed the sleeve 12, the ends of wires 7 and 8, in such a way that is prevented their sliding off the sleeve 12. The sleeve 12 is coupled with a screw-threaded side 13 realized at one end of the little cylinder block of manoeuvre 11, preferably conformed in a substantially cylindrical shape. At the other end of the little cylinder block of manoeuvre 11 is realized a cavity 14, delimited by a diaphragm 15 that divides it from the screw-threaded side 13.

The loops 5, 6 of the wire 7, 8 and at least the portion of the support 9 which is interested by the loops 5, 6 are connected, for example by repeated crossing passages, to a first portion 16 of the tubular body 2 that consists preferably of a segment of prosthesis of fabric disposed at annular configuration in such a way that the folds usually present in these fabrics result to be parallel to the axis 2a and then the radial contraction and the expansion of this portion 16 is facilitated. This first portion 16 is associated, for example by a suture, to the axial end of a second portion substantially cylindric 17 which is substantially coaxial to the first portion 16 in its annular disposition.

The little cylinder block of manoeuvre 11 and the portion of the wires 7, 8 that extend from little cylinder block of manoeuvre 11 to the support 9 are disposed externally to the tubular body 2.

The device for the application of the prosthesis according to the invention, indicated generally by the reference numeral 20, comprises a flexible tubular support, or sheath 21, that is insertable into the lumen of a blood vessel 4 distal to the tract to be substituted or internally lined with the prosthesis 1. This tubular support 21 is fitted, at its distal end, that is devised to be inserted into the blood vessel 4, with tools for retaining the support 9 and, at the proximal end that is devised to lie externally to the vessel 4, with control tools that are connected, through connecting tools that can slide inside the tubular support 21, to wires 7 and 8 to cause their sliding relatively to the support 9.

The tools for retaining the support 9 include, advantageously, a little retaining cable 22 which is slideable inside the tubular support 21 and that crosses predisposed holes realized at the distal end of the tubular support 21 and at that part of the end of the support 9 that is advantageously inserted inside the distal end of the tubular support 21; in this way the little retaining cable 22, by passing through both the support 9 and the tubular support 21, connects each other these two organs, contrasting the axial sliding of one in respect to the other, as shown in detail in figure 7. The axial sliding of the support 9 in direction of the tubular support 21 can be further contrasted by a beat ring 42 in a zone of the support 9 proximal to its end to be inserted into the tubular support 21.

The other end of the little retaining cable 22 comes out from the tubular support 21, in a zone of it that is close to its proximal end and therefore it lies, during the operation, externally to the blood vessel 4, and is fitted with a ring 23 that allows to cause the sliding of the little retaining cable 22 with respect to the tubular body 21 in the direction that cause the release of that little cable from the support 9 and from the tubular support 21 thus releasing the support 9 from the tubular support 21.

Advantageously in proximity to the ring 23, on the tubular support 21, a zone for handling 24 is provided in order to enhance the action of traction of the little retaining cable 22.

The controlling tools, in order to cause the sliding of the wires 7 and 8 relatively to the support 9, include a first handle 25 and a second handle 26 that are sited in correspondence of the proximal end of the tubular support 21 and that are connected to the little cylinder block of manoeuvre 11 by a first cable 27 and a second cable 28 that can slide internally to the tubular support 21 following the axial movement of the handles 25 and 26 in respect to tubular support 21.

More in detail, the first cable 27 presents, in correspondence with its distal end, i.e. the opposite end with respect to the handle 25, a folding 29 which brings its whole occupancy to be equal to two times the diameter in correspondence of this folding 29. The first cable 27 is inserted into the end of the little cylinder block of manoeuvre 11 opposite to the end from which is inserted the sleeve 12 and the folding 29 is sited in correspondence of a deficit 30 prepared in an intermediate zone of the lateral surface of the little cylinder block of manoeuvre 11. The cavity 14 presents, from the inserting end of the first cable 27 till the deficit 30, a lumen equal to nearly twice the diameter of the first cable 27, in such a way that the first cable 27 can be inserted and removed in the little cylinder block of manoeuvre 11 in spite of the presence of the folding 29. In the little cylinder

block of manoeuvre 11 from the same end of the insertion of the first cable 27, is inserted, after the insertion of the first cable 27, the second cable 28 that, with its presence, prevents the sliding off of the first cable 27.

The two handles 25 and 26 can jointly slide axially relatively to the tubular support 21 so as to operate the axial sliding of the little cylinder block of manoeuvre 11 in respect to support 9 retained at distal end of the tubular support 21 to cause a variation of the amplitude of the loops 5 and 6, otherwise they can slide one in respect to the other so as to allow the release of the second cable 28 from the little cylinder block of manoeuvre 11 and then the release of the first cable 27 from the little cylinder block of manoeuvre 11 so as to release the little cylinder block of manoeuvre 11 from the tubular support 21 when it is desired to leave the prosthesis in the blood vessel.

The first handle 25 presents, advantageously, a prolongation 31 which extends itself inside the handle 26 and that can be blocked by a screw 32, so as to solidarize the handle 25 and 26 between them, or so as to release one handle from the other according to the necessity.

Moreover, on the proximal end of the tubular support 21 is predisposed a screw 33 that allows to block the sliding of the first handle 25 relatively to the tubular support 21.

Advantageously, tools are provided for the guidance of the prosthesis into the blood vessel. Such tools include a cable guide 34 that is connected with its end to the tubular support 21 and that crosses axially the tubular body 2 of the prosthesis 1. The end of this cable guide 34, opposite to the end connected to the tubular support 21, is provided with an ogival body 35.

The tubular support 21 is mounted in an axially sliding way and blood-tightly, inside a tube 36 that is partially insertable inside the vessel or in a branch that can be closed around the tube 36, for example by a ligature 37, so as to realize the blood tightness during the insertion of the prosthesis 1 into the vessel 4.

The tightness between the tubular support 21 and the tube 36 can be obtained by positioning inside the tube 36 a disk gasket 38 which is crossed by the tubular support 21.

In order to avoid blood losses toward the external, tight disks 48 are provided also between the internal surface of the tubular support 21 and the cables 22, 27 and 28.

Advantageously tools for anchoring the tubular body 2 of the prosthesis to the lateral surface of the tubular support 21 during the insertion are also provided. Such anchoring tools include a button-hole 39 that can be obtained by a segment of thread for suture, that is connected to the tubular

body 2 of the prosthesis in proximity to its end opposite to the tract 16 and that is insertable into a predisposed fissure 40 realized in the lateral surface of the tubular support 21 in correspondence with the passage of the retaining cable 22, in such a way that the retaining cable 22 passes also through the button-hole 39 causing in such a way the lateral anchoring of the prosthesis that can be leaved in site by the partial sliding of the retaining cable 22 from the tubular support 21, as illustrated in detail in fig 13 and 15.

The application of the prosthesis according to the invention with the device described above is carried out as follows.

First of all the ogival body 35 is passed axially through the prosthesis with its first portion 16 properly dilated.

Then the prosthesis 1 is disposed in the conditions of minimal occupancy around its axis 2a by manually moving as much as possible the little cylinder block of manoeuvre 11 from the support 9, so that the loops 5 and 6 are maximally contracted. The little cylinder block of manoeuvre 11 is then linked to the end of the first cable 27 by disposing the folding 29 in correspondence of the deficit 30 and by inserting into the cavity 14 the second cable 28 in such a way that this cable 28 keeps blocked the first cable 27 into the little cylinder block of manoeuvre 11. At this point the little cylinder block of manoeuvre 11 is inserted into the distal end of the tubular support 21 till a tract of the end of the support 9 results also inserted in the distal end of the tubular support 21. The support 9 is then linked to the tubular support 21 by the insertion, through the support 9 and through the flexible support 21, of the end of the retaining cable 22. During the manoeuvre of insertion of the retaining cable 22, the button-hole 39 sited in proximity of the proximal end of the prosthesis, is inserted into the fissure 40 and crossed by the same retaining cable 22. In this way the prosthesis is still anchored to the distal end of the tubular support 21 and the tract 17 of the tubular body 2 is wrapped around the tubular support 21.

At this point the tubular support 21 is inserted into a vessel 4 distally to the zone of the vessel to be substituted or internally lined with the prosthesis 1, or inside a lateral branch of that vessel, in such a way to allow the positioning of the tube 36 in correspondence of a zone of the vessel that can be squeezed around the tube 36 so as to realize the haematic tightness. Then, by acting on the tubular support 21, its sliding relatively to the tube 36 is carried out in order to push the prosthesis along the vessel 4, as shown in detail in figures 12 and 13. The progression of the prosthesis along the blood vessel can be radiologically controlled in order to obtain the correct positioning of the pros-

thesis with the tract 16 proximal to the segment of the vessel to be substituted or internally lined with the prosthesis.

When the prosthesis is properly positioned, the handles 25 and 26 linked together by the screw 32 are actioned in order to push the cables 27 and 28 along the tubular support 21 in the direction that causes the dilatation of the loops 5 and 6 and then that achieves the adhesion of the prosthesis to the internal walls of the blood vessel (figures 8,9,14). When the degree of radial expansion of the portion 16 of the prosthesis is such that a tightness between the prosthesis and vascular wall is achieved, the tubular support 21 is released from the prosthesis. This release is achieved by unscrewing the screw 32 so that the handle 26 is separated from the handle 25 and then by partially sliding the second cable 28 and then the first cable 27 so as to release these cables from the little cylinder block of manoeuvre 11; at the end the little retaining cable 22 is partially slid causing the release of the support 9 and at the same time the release of the button-hole 39. In this way, the device for the application of the prosthesis is completely released from the prosthesis itself and can be removed from the blood vessel.

It should be noted that anytime during the procedure, by action on the handle 25 and 26 in the reverse way causing reduction of the loops 5 and 6 to its minimal occupancy, it is possible to correct the prosthesis position inside the vessel or to remove completely the prosthesis.

Whenever the vessel to substituted or internally lined with the prosthesis is surgically exposed it is possible to increase the adhesion of the portion 16 with the vessel walls by tying a ligature around the vessel in correspondence with the expanded portion 16.

When the tract of the vessel is surgically exposed and clamped, the prosthesis can be manually positioned by actioning, instead of the illustrated device, directly on the wires 7 and 8 to achieve the dilatation of the loops 5b and 6b that engages the prosthesis against the vessel internal walls.

As shown in figure 17, in order to improve the balance of the forces that act on the vessel is advantageous to predispose a second support 109, realized substantially as the support 9, and positioned in a zone diametrically opposite to the support 9 externally to the tubular support 2. The support 109 contains one or more wires 105, 106 with loops disposed substantially as the loops of the wires 5 and 6 and connected to an other little cylinder block of manoeuvre 11. Also the loops of wires 105 and 106 are connected to portions of the tubular body 2, as already described in reference to the loops of wires 5 and 6. The expansion of the

loops 105 and 106 will be obtained by a device as described or by a similar device with two first cables 27 and two second cables 28.

Moreover an annular body 3 can be provided which is similar to that already described, also at the other axial end of the tubular body 2.

In practice it has been observed that the prosthesis according to the invention realizes the prefixed aim, since allows to carry out the substitution or the inner lining of a vascular tract significantly reducing the blood flow interruption phase; moreover when the device for endovascular application is used there is no blood flow interruption phase at all, thus preventing paraplegia due to spinal cord ischemic necrosis, kidney and liver ischemic damages, without requiring by-pass or extracorporeal circulation between the proximal and distal vascular districts and without systemic heparinization, required when extracorporeal circulation is used.

Although the prosthesis according to the invention as well as the device for its application are intended in particular for descending thoracic aorta substitution in case of aneurisms, or dissection, also in rupture phase, and in case of traumatic aortic laceration, it could be advantageously used also for the prosthetic substitution of all tract of artery or vein whose lumen is at least partially patent.

Although the prosthesis according to the invention and the device for its application were prepared for the treatment of aneurisms and traumatic rupture of the thoracic aorta that can be used advantageously also for the prosthetic substitution of any tract of artery or vein whose lumen is at least partially patent.

The prosthesis according to the present invention, as well as the device for its application are susceptible to numerous modifications and variations, all falling within the scope of the inventive concept; furthermore all details may be substituted by technically equivalent elements.

In practising the invention any dimensions or materials may be used, providing that they are compatible with the specific use, according to the contingent requirements and the state of the art.

Where technical features mentioned in any claim are followed by reference signs, those reference signs have been included for the sole purpose of increasing the intelligibility of the claims and accordingly, such reference signs do not have any limiting effect on the interpretation of each element identified by way of example by such reference signs.

Claims

1. Vascular prosthesis for the substitution or internal lining of blood vessels of medium or large

- diameter, characterized by the fact of comprising a tubular body made of biocompatible material including, in proximity of one of its longitudinal ends, at least one body at annular development disposed substantially coaxial to said tubular body and radially expandible for the engagement of the tract of said tubular body, containing said body at annular development, against the internal walls of a blood vessel proximal to the segment to be substituted or internally lined, with the prosthesis, said body at annular development being constituted of at least one loop of at least one wire elastically flexible mounted slidably on a support associated to a lateral portion of said tubular body, said wire being sliding relatively to said support in order to vary the amplitude of said loop, tools being provided for contrast of the sliding of said wire relatively to said support in order to maintain the expansion or contraction, given to said loop by the controlled sliding of said wire relatively to said support, at the ceasing of the force generating the sliding.
2. Vascular prosthesis, according to claim 1, characterized by the fact that said tubular body presents an other body at annular development, realized in the same way as said body at annular development, in correspondence of the other longitudinal end.
 3. Vascular prosthesis, according to one or more previous claims, characterized by the fact that said body at annular development is constituted by at least two loops of two wires elastically flexible mounted slidably each on a support associated to a lateral portion of said tubular body, the two supports being sited in zones of said tubular body diametrically opposite one to the other, each wire of said wires being slidable relatively to the corresponding support in order to vary the amplitude of the related loop, tools being provided for contrast of the sliding of said wires relatively to said supports in order to maintain the expansion or the contraction, given to said loops by means of the controlled sliding of said wires relatively to said support, at ceasing of the force generating the sliding.
 4. Vascular prosthesis, according to one or more previous claims, characterized by the fact that said wire describes, internally to said tract of the tubular body, a double loop with a first tract coming out from said support along a direction inclined in respect to a plane which is transversal to said tubular body, with a second tract at annular development linked to said support in a zone spaced from the zone of coming out of said first tract, said second tract of the double loops developing in a plane substantially perpendicular to the axis of said tubular body, and with a third tract coming back into said support in a zone proximal to the zone of coming out of the said first tract.
 5. Vascular prosthesis, according to one or more previous claims, characterized by the fact that at least a wire includes two wires describing each a double loop with said first tract, said second tract and said third tract, the double loops of said two wires being spaced between them parallel to the axis of said tubular body.
 6. Vascular prosthesis, according to one or more of the above claims, characterized by the fact of including tools for positioning of one said double loops in respect to the other.
 7. Vascular prosthesis, according to one or more of the above claims, characterized by the fact that said tools for positioning include segments of wire connecting between them the second tract of said double loops in order to keep them in planes substantially parallel between them and perpendicular to the axis of said tubular body.
 8. Vascular prosthesis, according to one or more of the above claims, characterized by the fact that said support is constituted by a body substantially cylindric sited with its axis substantially parallel to the axis of said tubular body, said wires coming out laterally from said support to make said double loops.
 9. Vascular prosthesis, according to one or more of the above claims, characterized by the fact that the ends of the wires make said loops come out from an axial end of said support and are jointly associated to a little cylinder block of manoeuvre of said wires, said little cylinder block of manoeuvre being mobile at command relatively to said support for the sliding of said wires causing a variation of the amplitude of said loops.
 10. Vascular prosthesis, according to one or more of the above claims, characterized by the fact that said loops of the wires and at least the portion of said support involved by said loops is connected with a first portion of said tubular body, said first portion being constituted by a segment of prosthesis disposed at annular shape and radially expandible, said first portion

being associated to the axial end of a second portion substantially cylindric of said tubular body disposed substantially coaxially to the annular disposition of said first portion.

11. Vascular prosthesis, according to one or more of the above claims, characterized by the fact that said little cylinder block of manoeuvre and the portion of said wires extending from said little cylinder block of manoeuvre to said support are disposed externally to said tubular body.
12. Vascular prosthesis, according to one or more of the above claims, characterized by the fact that said wires are of harmonic stainless steel.
13. Device for the application, without the blood flow interruption, of a vascular prosthesis according to one or more of the above claims, characterized by the fact of including a tubular support flexible insertable into the lumen of a blood vessel distal to the tract to be substituted or internally lined with said prosthesis, said tubular support being provided, at its distal end predisposed to be inserted into the blood vessel, of retaining tools of said support and, at its proximal end, predisposed to lie externally to said vessel, of command tools connected, through tools sliding internally to said tubular support, to said at least one wire for its sliding relatively to said support for a variation of the amplitude of said at least one loop for the radial expansion or contraction of said body at annular development, being predisposed tools for deactivation of said tools of retaining of said support and said tools of connection being releasable at command by said at least one wire for the leaving in place of the prosthesis after its application.
14. Device, according to the claim 13, characterized by the fact of comprising tools of guidance of the prosthesis internally to the blood vessel.
15. Device according to one or more of the above claims, characterized by the fact that said guiding tools include a cable of guidance connected with one of its ends to said tubular support and axially crossing the prosthesis, the opposite end of said cable of guidance supporting an ogival body.
16. Device according to one or more of the above claims, characterized by the fact that said tubular support is inserted in such a way that is slidable axially, blood-tightly, internally to a

tube partially insertable into said vessel or in lateral branch of said vessel that can be occluded around said tube for the blood tightness during the insertion of the prosthesis

17. Device according to one or more of the above claims, characterized by the fact that said retaining tools include a retaining cable slidable internally to said tubular support, said retaining cable connecting with its distal end said tubular support to said support, said retaining cable coming out with its proximal end from said tubular support externally to the vessel and being slidable at command along said tubular support to release said support from the distal end of said tubular support.
18. Device according to one or more of the above claims, characterized by the fact that said command tools include at least one handle connected with the proximal end of said tubular support and connected to said at least one wire by a cable sited slidably internally to said tubular support, said handle being axially movable relatively to said tubular support for the sliding of said at least one wire relatively to said support.
19. Device according to one or more of the above claims, characterized by the fact that said command tools include a first handle and a second handle connected to the proximal end of said tubular support, said first handle being connected to a first cable extending internally to said tubular support till to a little cylinder block of manoeuvre fixed to that at least one wire and said second handle being connected to a second cable extending internally to said tubular support and connecting said first cable to said little cylinder block of manoeuvre, said first and second handle being jointly movable relatively to said tubular support for the sliding of said at least one wire relatively to said support or individually to the release of said cable from said little cylinder block of manoeuvre for the leaving of the prosthesis internally to the vessel.
20. Device according to one or more of the above claims, characterized by the fact of including tools for the fixation of the prosthesis to the lateral surface of said tubular support.
21. Device according to one or more of the above claims, characterized by the fact that said fixation tools include a fixing button-hole connected to said prosthesis and insertable into a fissure defined in the lateral surface of said

tubular support, said button-hole being crossable by said retaining cable for the retention removable, at the action of removal of said retaining cable, of said prosthesis in proximity of said tubular body.

5

22. Device according to one or more of the above claims, characterized by the fact of including tools for tightness interposed between said cables and the internal surface of said tubular support.

10

15

20

25

30

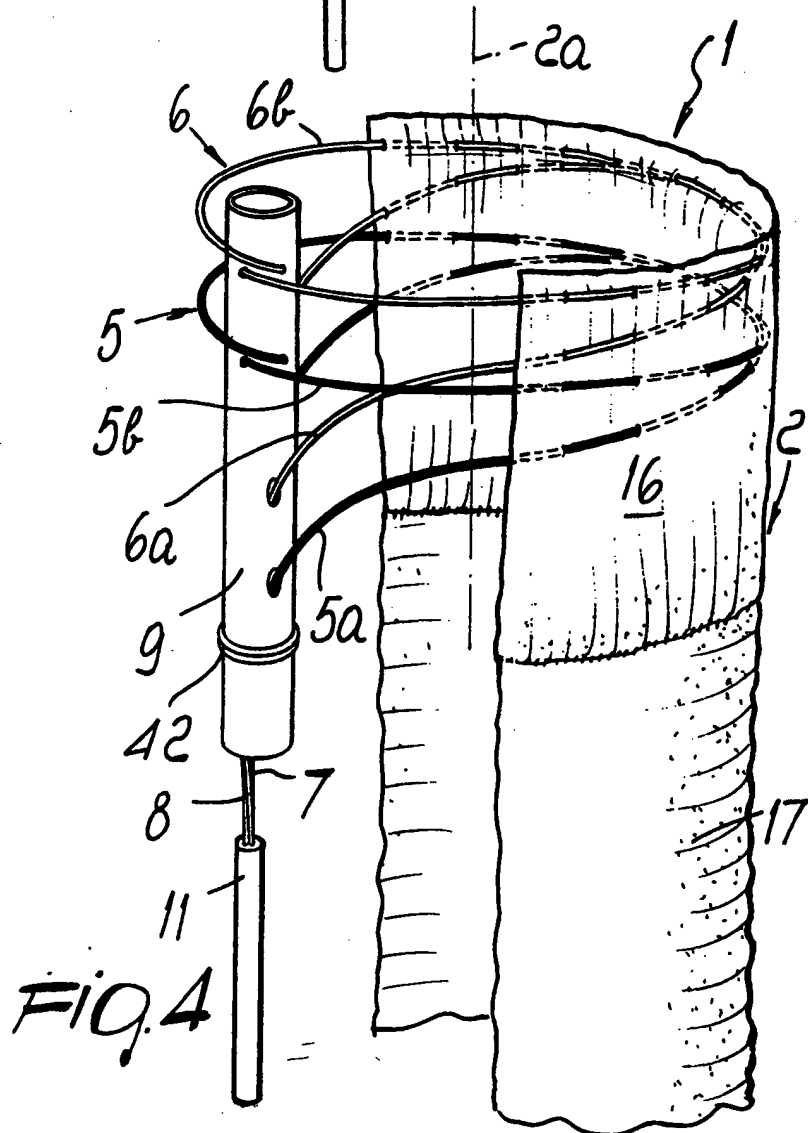
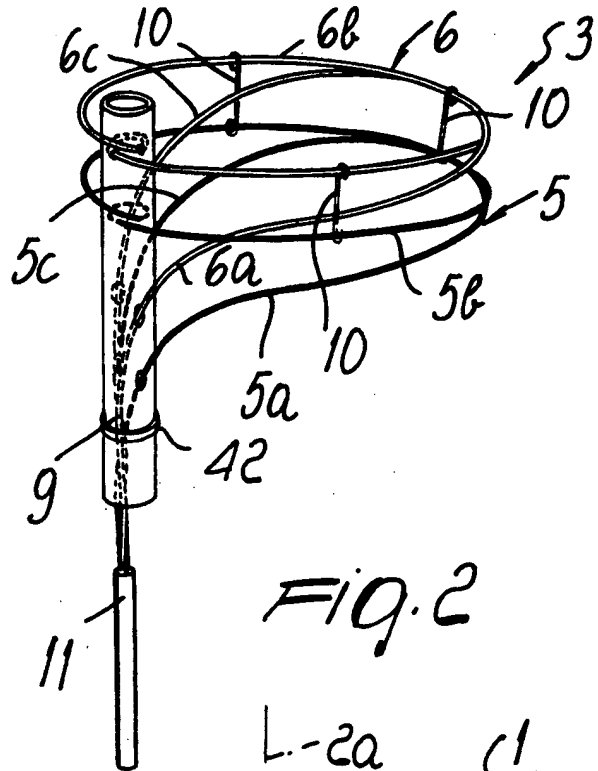
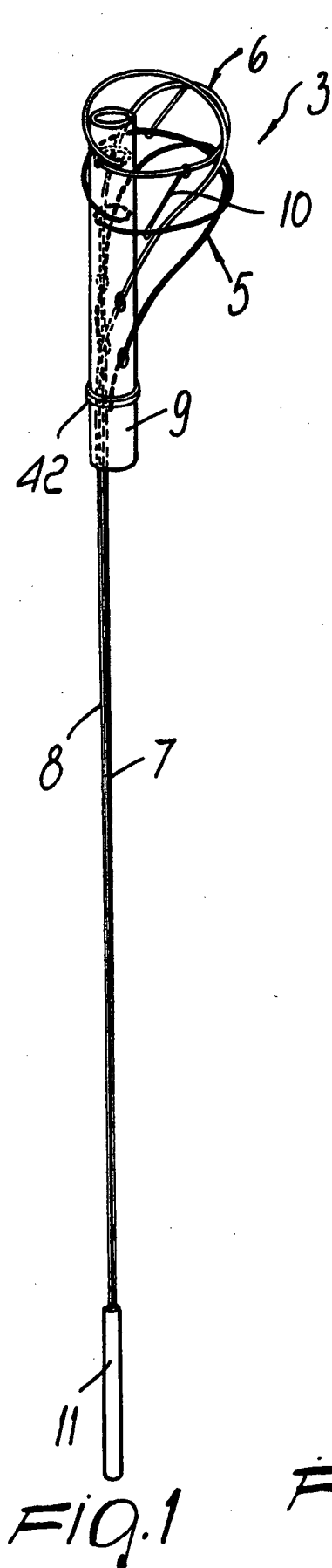
35

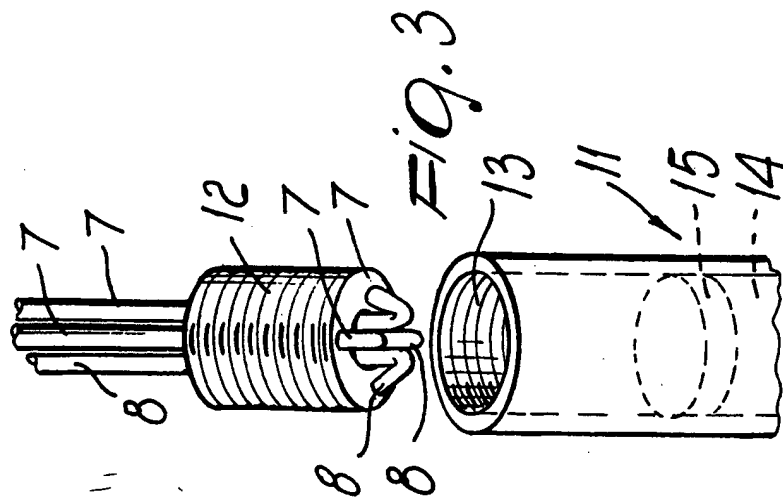
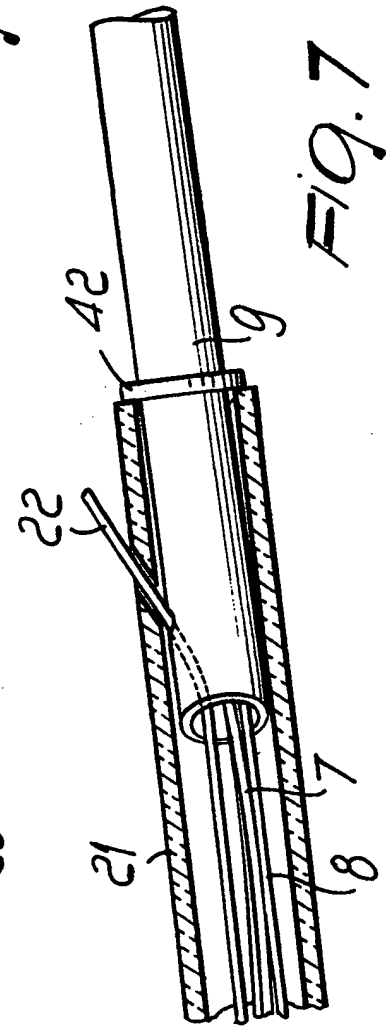
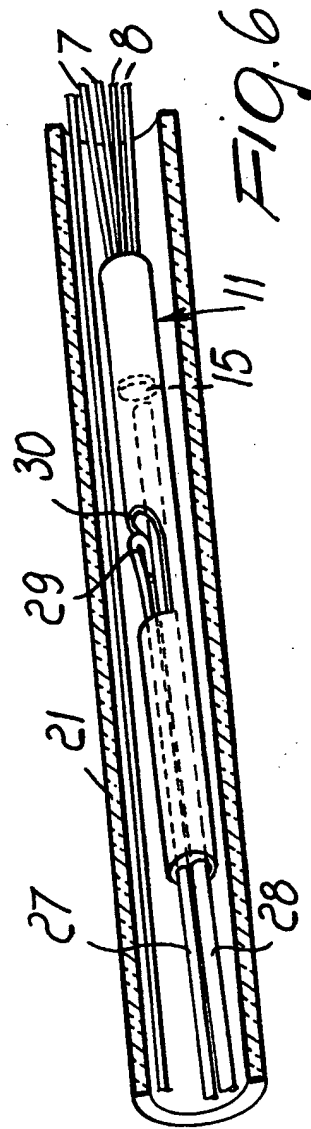
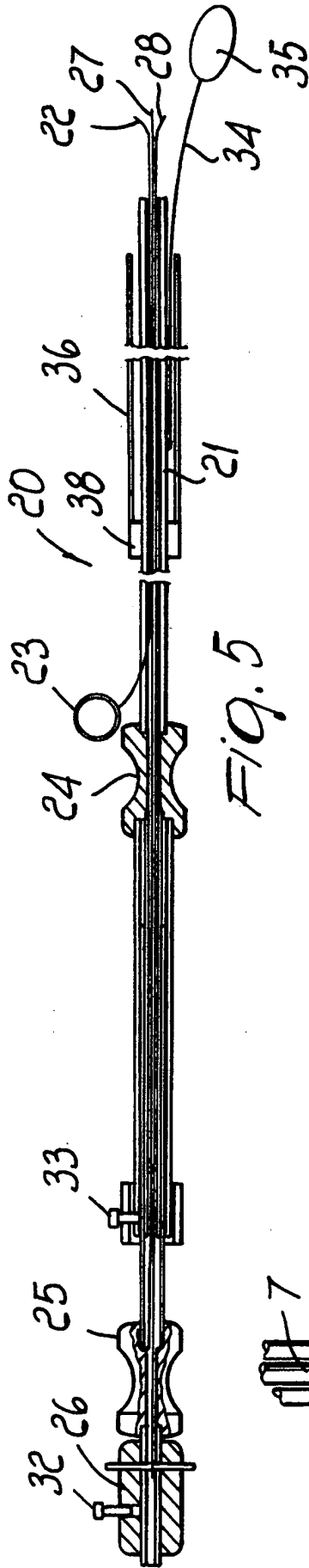
40

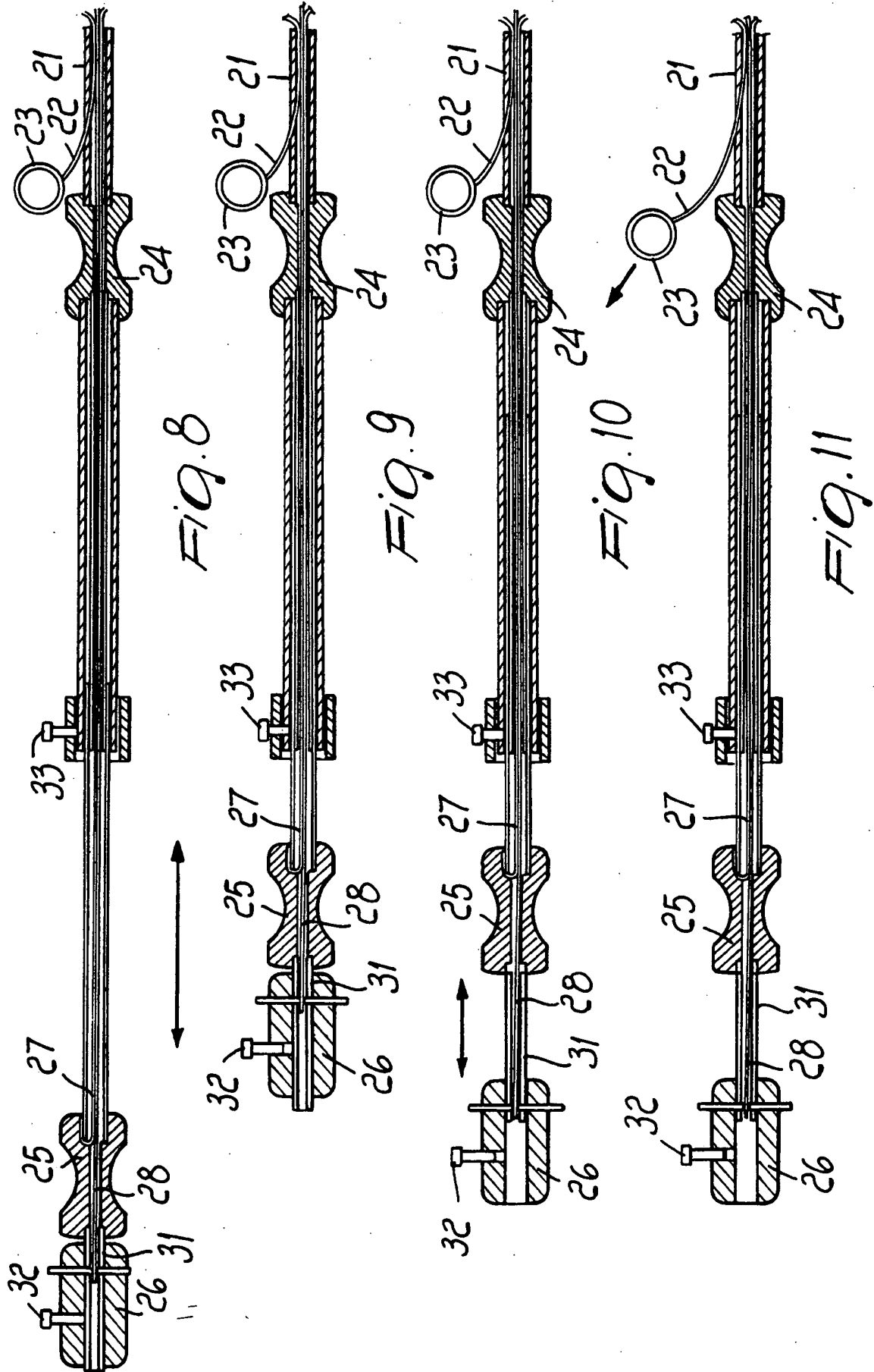
45

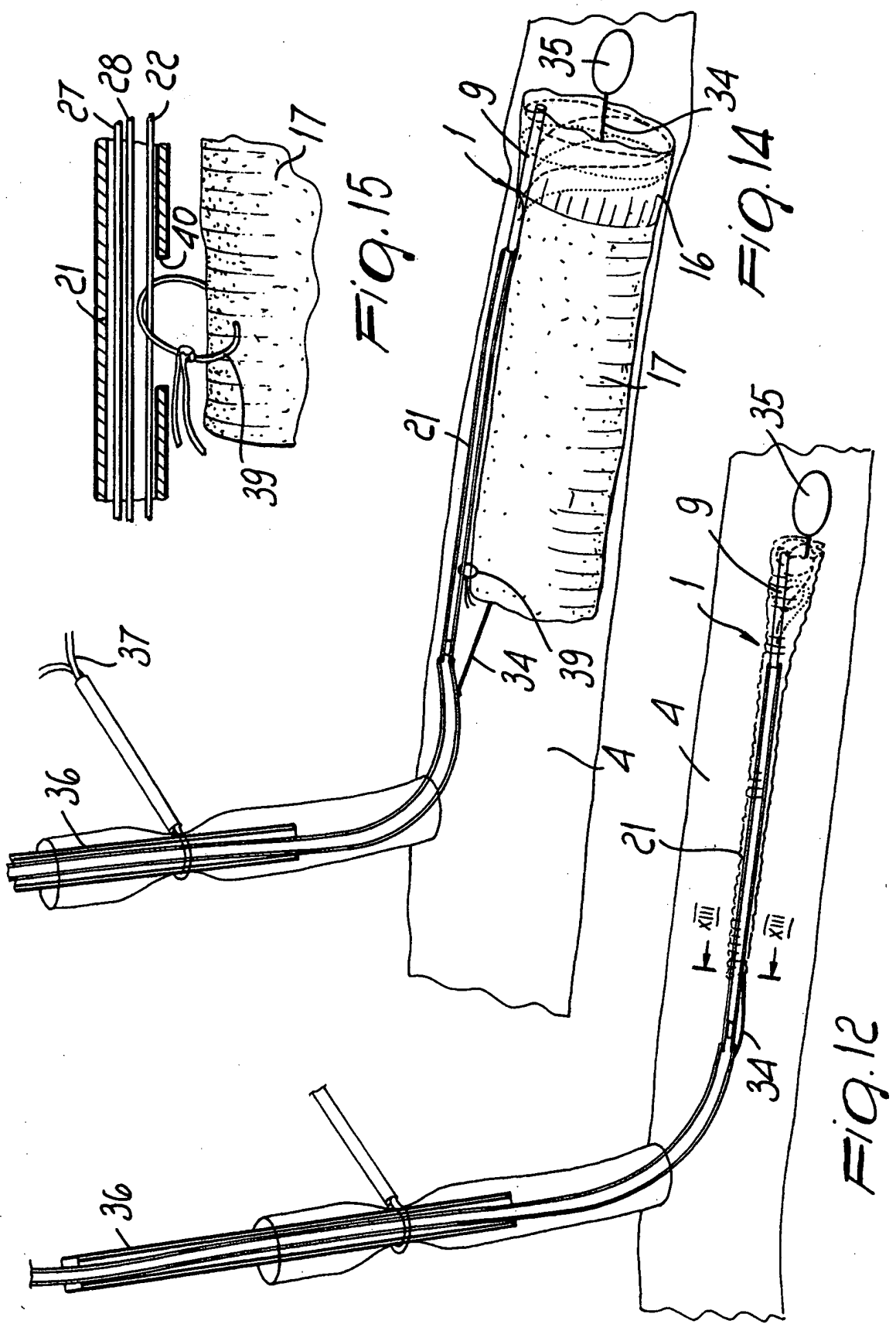
50

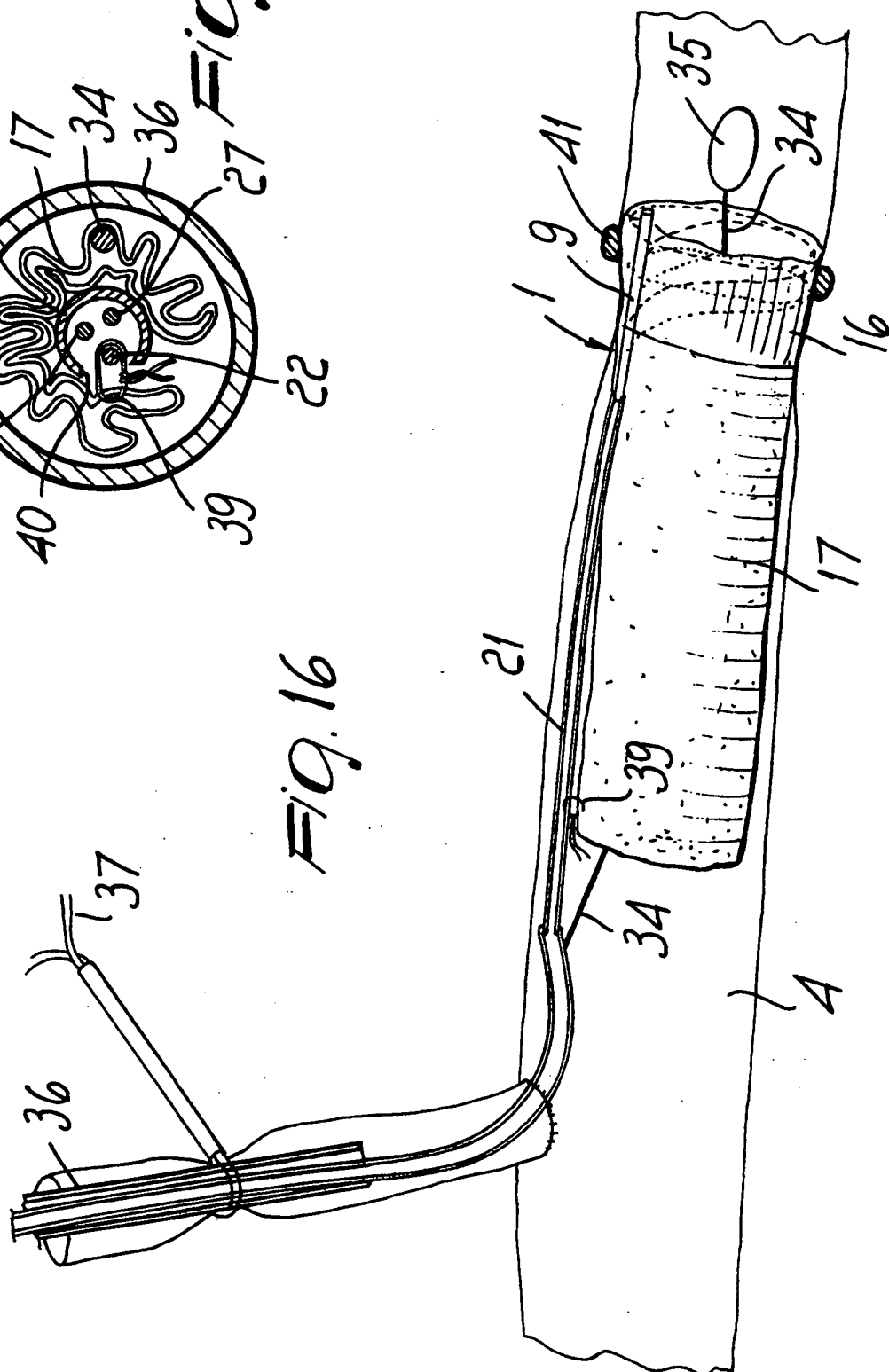
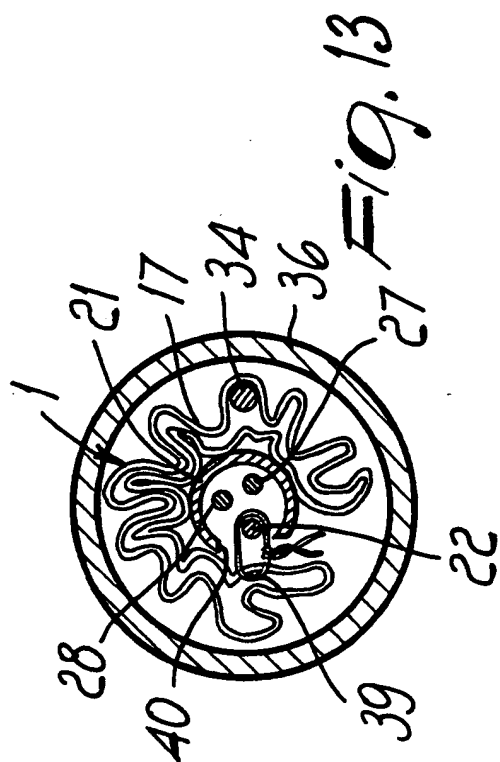
55











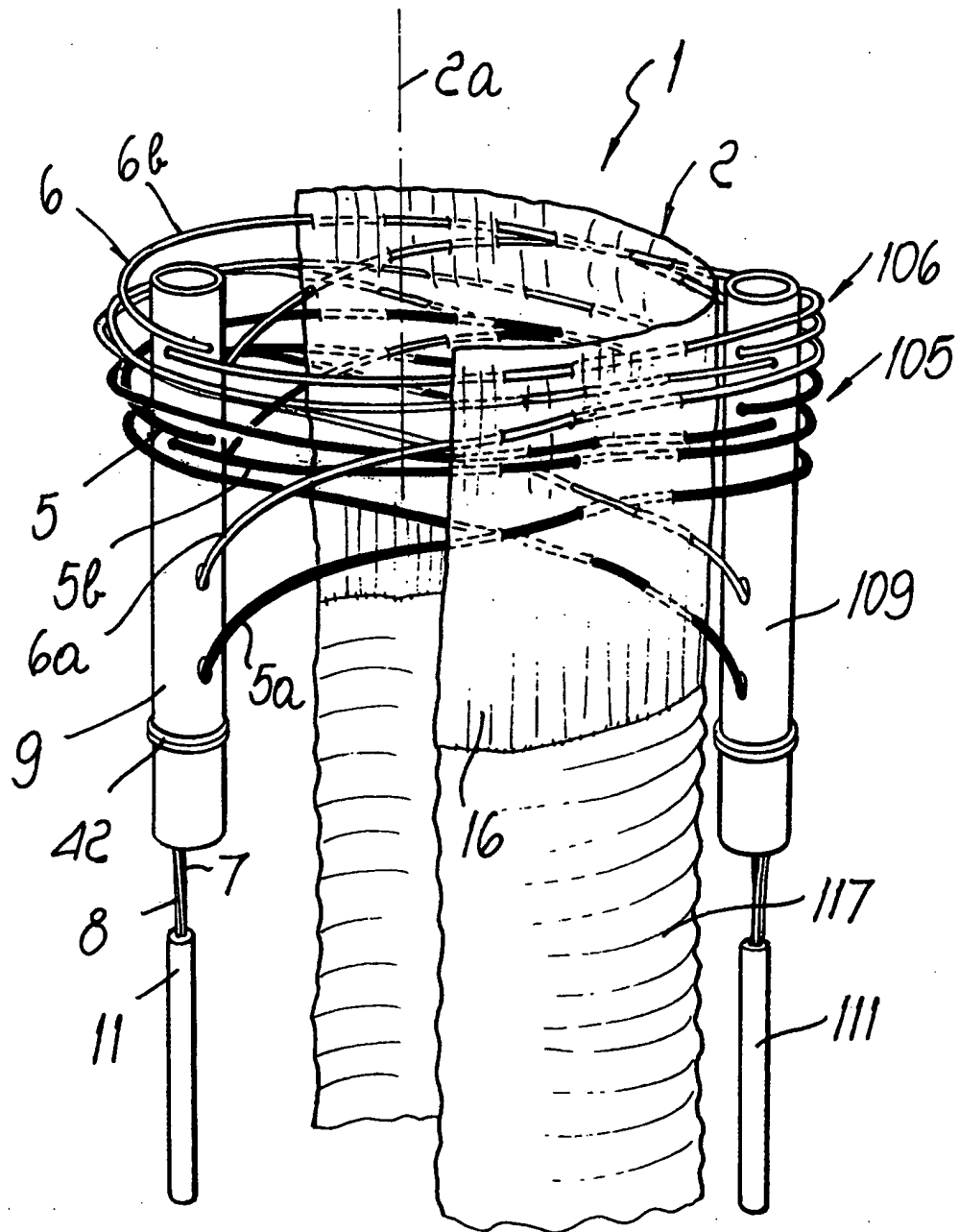


Fig. 17



European Patent
Office

EUROPEAN SEARCH REPORT

Application Number
EP 95 10 0498

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X	DE-A-28 05 749 (CHOUDHURY) * page 9, line 14-20 * * page 10, paragraph 1; figures * ----	1,13-16	A61F2/06
A	EP-A-0 544 485 (COOK INCORPORATED) -----		
			TECHNICAL FIELDS SEARCHED (Int.Cl.6)
			A61F
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 20 April 1995	Examiner Steenbakker, J
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure F : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons ----- & : member of the same patent family, corresponding document			

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☒ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.